

Comprehensive Guidelines for the Responsible Conduct of Researchers

Gregory Brock, Department of Family Studies, University of Kentucky, USA

Sandra Sutter, Department of Family Studies, University of Kentucky, USA

Ada Sue Selwitz, Office on Research Integrity, University of Kentucky, USA

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In 1989, the Department of Health and Human Services (DHHS) through the Public Health Service defined research misconduct and established regulations for reporting scientific misconduct among awardee and applicant institutions (1). The focus of this regulation was on fabrication, falsification, and plagiarism. More recently DHHS has shifted emphasis toward preventing misconduct and to the promotion of Responsible Conduct in Research (RCR).

Success in implementing regulatory initiatives on research integrity has been stymied by several factors. There is disagreement about the extent of research misconduct. Steneck (2) reported that fewer than 200 cases of misconduct have been documented by federal government research investigation offices over the past 20 years. Indirect evidence also cited by Steneck, however, suggests that misconduct may occur far more frequently.

Additionally, there is a lack of clarity about what amounts to research misconduct. In 1989, the term focused on, "...fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research."(1). Defining deviant practice as well as what is common practice is particularly challenging in view of the rapid development now occurring within many scientific disciplines—what was deviant can become common practice. Plus, collaboration among academic disciplines, between universities and industry, between universities and government, and between international research teams creates new syntheses that further complicate our understanding of what constitutes common practice. In an effort to address these issues, regulators have turned to requiring training of researchers as one means of communicating that the incidence of misconduct is troubling. Training objectives also clarify what amounts to misconduct.

On December 1, 2000, the DHHS Office of Research Integrity adopted and published the final PHS Policy on Instruction in the Responsible Conduct of Research that delineates RCR training requirements to all research investigators applying for or using PHS funds and their institutions (3). Although nine core areas of instruction are specified, the policy does not establish the exact content in the form of standards and principles within each area. In complying with this mandate, each institution will be responsible for its own content.

Much attention in the RCR literature has been directed to standards within specific areas, such as authorship, peer review, and collaborative practices. Presentations at national conferences and

institutional committees have addressed RCR practice standards. As well, many professional associations have established standards of conduct within their ethical codes. Institutional policies such as *Guidelines for the Conduct of Research at the National Institute of Health* have also incorporated a selection of RCR topics (4). However, no single set of principles encompassing all aspects of responsible conduct of research exists in unified form.

Grinnell (5) pointed out that "...promoting responsible conduct of science requires a clear description of what doing science entails." In addressing why standards are important, Frankel (6) discussed the need of the general public for accountability in science, and how a set of standards not only meets this need but also increases trust in the scientific community. Frankel noted specific benefits to establishing ethical standards: Standards provide an enabling document, professional socialization, public accountability, gain public trust/support, improve public relations, self-preservation, deterrence, professional support, and are a source of public policy. Standards also provide guidance when an ethical course of action is unclear. Mastroianni and Kahn (7) point out that training students in the basics of RCR is crucial to the continued maintenance of public trust in the scientific community by cultivating the integrity of research practices. However, results on the effectiveness of RCR training thus far are inconclusive (8, 9). Brown and Kalichman (9) offer the interpretation that a lack of consensus on what constitutes misconduct may contribute to the lack of clarity on the effectiveness of training.

Frankel (10) advocates the development of research standards as the single most important step in promoting scientific integrity and handling misconduct. Faced with the new training requirements established by the PHS, this step is particularly important for promoting and supporting a climate of integrity at the organizational level that can function in a reciprocal fashion to influence and be influenced by individual actions.

Initially, the purpose of the document presented here was to provide a comprehensive set of guiding principles to serve as a basis for RCR training at the University of Kentucky. Content analysis was applied to an exhaustive list of behavioral guidelines identified in a thorough review of the research integrity literature including ethics codes of professional

associations. Guidelines were then sorted into discrete thematic categories. These categories were called principles because they identified core values of research practice. Three groups of principles emerged from the analysis: General, Professional, and Focused. Subprinciples also were defined that served to elucidate contemporary issues rather than merely exemplifying situations in which the principles might apply. A series of revisions were made after obtaining feedback from research colleagues and university administrators.

What emerged was a comprehensive set of guidelines for the conduct of researchers more akin to a code of conduct for a profession (see attached guidelines). These guidelines provide a broad-based foundation for the safe and effective practice of research across disciplines, settings, methods, and questions. Our intent in presenting them here is to increase the awareness and sensitivity of institutional policy makers to the many issues that researchers must attend to in the conduct of their professional responsibilities. By presenting the results of our analysis, we wish to further the discussion about the content of RCR training.

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References

1. Department of Health and Human Services, Public Health Service. Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science. Federal Register Vol. 54 No. 151 Tuesday, August 8, 1989.
2. Steneck, N. Assessing the Integrity of Publicly Funded Research: A Background Report. Paper prepared for the Department of Health and Human Services, Office on Research Integrity Research Conference on Research Integrity on November 2000, Bethesda, MD.
3. PHS Policy on Instruction in the Responsible Conduct of Research, Department of Health and Human Services, Public Health Service, Office of Research Integrity. Available at URL: <http://ori.dhhs.gov/html/programs/rcrcontents.asp>
4. American Association of Medical Colleges. Developing a code of ethics in research: A guide for scientific societies, executive summary. Conference Materials of the Public Responsibility in Medicine and Research; 1997 May 13-14; Bethesda, Maryland.
5. Grinnell, F. Ambiguity, trust, and the responsible conduct of research. *Science and Engineering Ethics*, 1999; 5 (2): 205-214.

6. Frankel, M. S. Developing ethical standards for responsible research: Why? Form? Functions? Process? Outcomes?, *Journal of Dental Research* 1996; 75 (2): 832-835.
7. Mastroianni, A. C., & Kahn, J. P. The importance of expanding current training in responsible conduct of research. *Academic Medicine* 1998; 13 (12): 1249-1254.
8. Eastwood, S., Derish, P., Leash, E., & Ordway, S. Ethical issues in biomedical research: perceptions and practices of postdoctoral research fellows responding to a survey. *Science and Engineering Ethics* 1996; 2: 89-114.
9. Brown & Kalichman. Effects of training in RCR: A survey of graduate students in experimental sciences. *Science and Engineering Ethics* 1998; 4: 487-498.
10. Frankel, M. S. Scientific community must set the standards. *Forum for Applied Research and Public Policy*, Spring 1998

Guidelines for the Responsible Conduct of Researchers

Preamble: Advancing the scientific record is the noble task of those who conduct research. In large part the quality of that record is the product of inquiry. Ranging well beyond the conduct of research however is the realm of activities constituting the work of researchers that influences the public trust, that affects global well-being, and that indirectly affects the scientific record. The guidelines presented here define expectations so that researchers uphold the highest ethical standards by practicing within the bounds of both effectiveness and safety.

Important, sustaining values that support humankind and global well-being serve as the basis for three groups of principles and sub-principles. (1) General principles apply to all research contexts. (2) Professional principles define relations among researchers and practices that constitute the scientific method. (3) Focused-principles address discrete aspects of research practice for particular investigations, research contexts, or scientific disciplines. Sub-principles elucidate contemporary issues rather than identifying the component issues of any principle.

Where governmental laws contradict these guidelines, researchers are cautioned to seek consultation from appropriate authorities and colleagues. Resolution is not always possible, consequently, researchers act so as to benefit the greater good even if that path demands personal sacrifices.

In an effort to create a research climate worthy of the public trust, it is incumbent upon researchers to report any breach of these guidelines to an appropriate authority. Where there is no relevant authority, researchers are obliged to focus public media attention on wrong doing.

These guidelines apply to professional and amateur researchers, students, research technicians, research administrators, as well as private, public, and governmental research agency personnel.

General Principles

General Principle 1: Commitment to Society and to Global Well-being

Researchers protect the interests of society within a broader commitment to global well-being. They recognize that the public has entrusted them to uphold the integrity of the scientific record.

- 1.1 Researchers do not obligate themselves to withhold research findings that may jeopardize the health or well-being of others.
- 1.2 Researchers take active steps to prevent the misuse of their findings that may jeopardize the well-being of others.
- 1.3 Researchers take active steps to correct errors or oversights in proposing, conducting, or reporting research.
- 1.4 Researchers present themselves to the public in a competent, sincere, and trustworthy manner.

General Principle 2: Commitment to Competency

Researchers are aware they are responsible for maintaining professional competency and remaining knowledgeable within their areas of expertise.

- 2.1 Researchers conduct their work within the scope of their own training and knowledge base.
- 2.2 Researchers recognize they are vulnerable to stress and impairment. When stress or impairment interferes with their ability to conduct professional responsibilities, researchers seek assistance.
- 2.3 Researchers ensure that all persons who assist in the conduct of their research are adequately trained and perform their responsibilities competently.
- 2.4 Researchers inform their work with views, values, and co-workers from diverse sources.
- 2.5 Researchers foster a scientific community in which discrimination based on gender, race age, sexual orientation, religious affiliation, ethnic or national origin does not occur.

General Principle 3: Understanding Laws, Regulations, and Policies

Researchers are aware of and stay informed of professional, institutional, and governmental regulations and policies in proposing, conducting, and reporting research.

- 3.1 Researchers take active steps to resolve discrepancies when policies or regulations are unclear or contradict one another.

General Principle 4: Conflicts of Interests

Researchers are cognizant that conflicts of interest occur in the context of professional activities and they recognize and avoid them.

- 4.1 When researchers cannot avoid real or perceived conflicts of interest, they seek consultation and take active steps to minimize bias, flawed judgment, harm, or exploitation.

Professional Principles

Professional Principle 5: Peer Review

Researchers respect others' rights to have work reviewed in a confidential, timely, and objective manner.

- 5.1 Researchers assess and disclose multiple roles or allegiances which may undermine the confidential and fair review of others' work.
- 5.2 Researchers take active steps to protect the integrity of review materials and guard the intellectual property of others.

Professional Principle 6: Research Management and Data Access

Researchers clearly and authentically record data and methods. They protect the integrity of their research materials. They make data, methods, and materials available to others for analysis or replication.

- 6.1 Researchers select materials appropriate for data acquisition, recording, and storage.
- 6.2 Researchers stay informed of and implement policies for appropriate storage and disposal of research materials.
- 6.3 Researchers take active steps to select methods and materials that protect research participants' right to privacy.
- 6.4 Researchers take active steps to safeguard data when using electronic or Internet-based methods.
- 6.5 Researchers are cognizant of the ownership of their research data, methods, and findings.

Professional Principle 7: Commitment to Credibility

Researchers engage in practices that are currently accepted within the scientific community to propose, conduct, and report research.

- 7.1 Researchers practice honest stewardship of their research resources and use recognized accounting methods.
- 7.2 Researchers do not conduct their professional responsibilities in a manner that is intentionally deceitful or with reckless disregard for the truth.
- 7.3 Researchers who witness or suspect fraud or misconduct follow established procedures to preserve the integrity of the scientific record.
- 7.4 Researchers accused of fraud or misconduct do not harass those believed or known to have made accusations against them.
- 7.5 Researchers do not misrepresent their work by omitting data that changes the meaning or significance of their findings.
- 7.6 Researchers do not fabricate or falsify data.
- 7.7 Researchers do not present or publish component findings of a larger body of work if misunderstanding may result or to conceal findings.

Professional Principle 8: Mentoring, Training, and Supervisory Relationships

Researchers nurture the intellectual, technical, ethical, and career development of their trainees, supervisees, and students.

- 8.1 Researchers recognize that trainees, supervisees, and students have needs unique to their individual strengths and limitations. Researchers provide guidance, constructive feedback, and assistance that matches the changing needs of each trainee, supervisee, or student.
- 8.2 Researchers establish clear and appropriate rules and boundaries in their relationships with trainees, supervisees, and students.
- 8.3 Researchers do not engage in sexual harassment, disrespect the character of, or impede the progress of their trainees, supervisees, and students.
- 8.4 Researchers recognize that exploitation is a risk in relationships where differences in power exist. They avoid conflicts of interest and dual relationships. Sexual interaction with subordinates is avoided.
- 8.5 Researchers take active steps to inform trainees, supervisees and students of supervisors' responsibilities to avoid dual relationships.

Professional Principle 9: Authorship and Publication Practices

Researchers respect the intellectual property rights of others.

- 9.1 Researchers attribute credit for others' words and/or ideas in proposing, conducting, or reporting their own work.
- 9.2 Researchers facilitate discussion and set ground rules early in collaborative relationships regarding authorship assignment.
- 9.3 Researchers assume responsibility for the accuracy of research reports for which they claim full or co-authorship.
- 9.4 Researchers preserve the integrity of the scientific record by taking active steps to correct errors in the publication of their findings.
- 9.5 Researchers do not submit or publish previously published materials without appropriate citation.
- 9.6 Researchers respect the privacy of others' unpublished work.

Professional Principle 10: Responsibilities to Colleagues and Peers

Researchers recognize they are members of the scientific community and respect the contributions of others to the scientific record.

- 10.1 Researchers clarify early in a collaborative project the expectations and responsibilities among those involved.

- 10.2 Researchers do not impede the progress of others' work.
- 10.3 Researchers protect the integrity of intellectual property and research materials when reviewing others' work.
- 10.4 Researchers take active steps to maintain positive relations among team members and to seek consultation if necessary to resolve interpersonal conflicts.

Focused Principles

Focused Principle 11: Protection of Human Participants

Researchers respect the dignity of human participants and take active steps to protect their well-being. They follow institutional, professional association, and governmental ethical and regulatory guidelines.

- 11.1 Researchers ensure that each participant gives voluntary and informed consent regardless of age, race, gender, ethnic or national origin, sexual orientation, mental or physical health status, or incarceration.
- 11.2 Researchers take active steps to evaluate and to minimize potential risks to participants.
- 11.3 Researchers respect each participant's right to privacy, and they take active steps to protect confidentiality of data or other disclosures.
- 11.4 Researchers take active steps to achieve an equitable balance of benefits and risks to each participant.
- 11.5 Researchers honor fairness and equity in the selection of research participants.

Focused Principle 12: Care and Use of Animals for Research

Researchers are stewards of animals used for research. They follow institutional, professional association, and governmental ethical and regulatory guidelines.

- 12.1 Researchers substitute inanimate materials and processes for animals where appropriate. When this is not possible, researchers make active efforts to use species that may be less susceptible to pain and distress.
- 12.2 Researchers take active steps to use procedures which reduce the incidence and/or severity of pain and distress experienced by animals.
- 12.3 Researchers take active steps to reduce the use of animals to the minimum number necessary to yield valid answers to their research questions.

Focused Principle 13: Commitment to Native Populations and Other Identifiable Groups

Researchers respect the rights and protect the interests of Native populations and other identifiable groups.

- 13.1 Researchers who work with Native populations and other identifiable groups recognize that to minimize risks and to maximize benefits to individuals and to populations themselves there is value in obtaining the advice, participation, and viewpoints of those individuals and populations in formulating research questions, designing research methods, collecting and analyzing data, and in reporting results.
- 13.2 Researchers recognize that consent from or consultation with group authorities or representatives is sometimes necessary before obtaining consent from individuals within Native populations or other identifiable groups.
- 13.3 Researchers take active steps to distinguish individual property both tangible and intangible from collective property owned by Native populations or other identifiable groups.
- 13.4 Researchers take active steps to reduce the risk to Native populations or other identifiable groups that result from misuse of their research findings.

Focused Principle 14: Genetic Research and Technology

Researchers strive to preserve and protect global well-being from the unintended consequences of genetic research.

- 14.1 Researchers involved in genetic research take active steps to identify potential risks and benefits to research participants. They inform participants of the possibility that risks may not yet be identified.
- 14.2 Researchers take active steps to protect the confidentiality of genetic materials collected from human participants and do not allow the use of these materials for purposes which may discriminate against or harm an individual or group of individuals.
- 14.3 Researchers are sensitive to social, physical, psychological and environmental factors that may influence individuals' consent to participate in genetic research.
- 14.4 Researchers inform individuals, their families, and Native and other identifiable populations of the disruptive influence that genetic research may have on their lives. They take active steps to minimize disruptions.
- 14.5 Researchers are cognizant of the increasing complexity of the ethical concerns about genetic research. They stay informed of the developing research guidelines as well as the public discourse about genetic research.
- 14.6 Researchers actively participate in the development and refinement of ethical standards in this area.

